GOVERNMENT OF INDIA
COMMERCE AND INDUSTRY
LOK SABHA

UNSTARRED QUESTION NO:2456
ANSWERED ON:09.05.2016
Issue of Compulsory Licences
Udhayakumar Shri M.

Will the Minister of COMMERCE AND INDUSTRY be pleased to state:

(a) whether as per recent media reports, India has privately assured that it will not issue anymore compulsory licences allowing local firms to override patents and make cheaper copies of drugs developed by global drug majors;

(b) if so, the reaction of the Government thereto;

(c) whether India is likely to grant licences under certain conditions such as public health emergencies to ensure such access to affordable medicine; and

(d) if so, the details thereof?

Answer

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THE MINISTER OF STATE (INDEPENDENT CHARGE)
OF THE MINISTRY OF COMMERCE & INDUSTRY
(SHRIMATI NIRMALA SITHARAMAN)

(a)&(b): No, Madam. No such assurance has been given by the Government of India. Any such media reports are factually incorrect. A clarification in this regard has already been issued by the Department of Industrial Policy and Promotion through the Press Information Bureau on 22.3.2016 (copy enclosed). Even as Government of India is conscious of the need to spur innovation and protect individual rights, it retains the sovereign right to utilize the flexibilities provided in the international IPR regime.

(c)&(d): The Patents Act, 1970 ('the Act') provides for issue of compulsory licenses under certain conditions contained in chapters XVI and XVII of the Act. A Compulsory License (CL) can be issued only if the conditions prescribed under the Act are satisfied.

Under section 84, a CL can be issued by the Controller General of Patents, Designs and Trademarks (CGPDTM) on the grounds that reasonable requirements of the public with respect to the patented invention have not been satisfied, or that the patented invention is not available to the public at a reasonably affordable price, or that the patented invention is not worked in the territory of India. Under Section 91, CL can be issued for a related patent. Under Section 92, the CGPDTM can issue CL based upon a notification issued by the Central Government under circumstances of national emergency or of extreme urgency or in a case of public non-commercial use. Under Section 92 A, the CGPDTM can issue CL on application for manufacture and export of patented pharmaceutical product to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems. In addition, Chapter XVII of the Act provides for use of inventions for the purposes of government and acquisition of inventions by Central Government.

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